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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,040	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45 and 49-88* is/are rejected.

7)☒ Claim(s) *46-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *01 March 2002* is: a)☐ approved b)☒ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The two Preliminary Amendments filed 3/1/02 have been entered as Paper Nos. 5 and 6. Changes to the abstract, specification and Figures 1, 3, 4A-4C, 5A-5B, 6A-6B, 9, 10A-10B, 11A and 12A-12B have been approved by the examiner. Claims 1-44 have been canceled and new claims 45-48 have been added. The Preliminary Amendment filed 3/14/03 has been entered as Paper No. 7. Changes to the title have been approved by the examiner. New claims 49-88 (misnumbered claims 45-84 have been renumbered as 49-88) have been added.

Drawings

2. The amendments made to Figures 11B-11D have not been approved by the examiner, and are objected to. The lead line of reference number 28 is incorrectly drawn to the outside edge, which is what reference number 26 designates, rather than to the upper surface (see amended Figure 11A).

3. The drawings are objected to because in Figure 9, the reference number "40" pointing to the disc annulus should be changed to --42--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 46 and 48 are objected to because of the following informalities:

a. Claim 46, line 2, "18" should be deleted.

b. Claim 48 should be rewritten following the Markush format of listing of elements.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 49-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following claim limitations from the new claims are considered new matter:

a. Claim 49: "therapeutically or prophylactically treating", "*at least one* first dimension", "*at least one* second dimension" and "*at least as large* as said aperture dimension". Applicant never discloses applicant's annulus repair device as having more than one first and second dimensions, as defined. Also, the invention is disclosed as having a second dimension larger than the aperture (see any of the figures), not as large as the aperture.

b. Claims 55 and 56: how "aperture dimension" is defined/measured.

c. Claim 58: "polyethylene".

d. Claim 60: "polytetrafluoroethylene". Applicant discloses expandable polytetrafluoroethylene (ePTFE).

e. Claim 62: "shape memory material".

f. Claim 63: "nitinol".

g. Claims 67-69: time of "aperture dimension" measurement.

h. Claims 72-74: "at least a portion of". Applicant discloses the device as "a patch of human muscle fascia or any other autograft, allograft or xenograft" in column 4, lines 18-19, which means that the entire device is made from the autograft, allograft, or xenograft. There is no support for only a portion of the device being made therefrom.

i. Claim 86: "*at least one* first dimension", "*at least one* second dimension" and "*at least as large* as said aperture dimension".

j. Claim 87: "at least partially", "*at least* one dimension" and "*at least as large* as said aperture". Applicant never discloses the device only partially being delivered through the aperture.

k. Claim 88: "at least partially spans". Applicant never discloses the device as only partially spanning the aperture.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 45 is rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. (USPN 6,224,630, as cited in applicant's IDS).

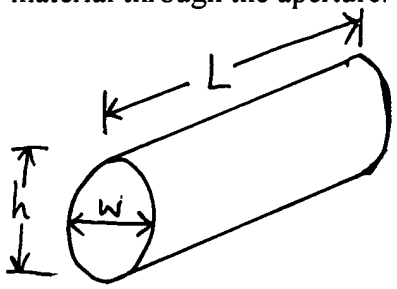
Bao et al. discloses an annulus stent for repairing an aperture in an intervertebral disc with all the elements of claim 45. See column 7, lines 62-67 for the annulus stent having a spool-like configuration. The spool shaped stent comprises the centralized vertical extension, wherein one enlarged end portion is the upper section and the other enlarged end portion is the lower section. The section between the enlarged end portions is the recess that enables the annulus stent to form a compatible fit with the edges of an aperture.

9. Claims 49-62, 67-71 and 75-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al.

Independent claims 49, 86, 87 and 88 contain limitations that constitute new matter. Therefore, the claims do not receive benefit of the earlier filing dates of the parent and provisional applications. The effective filing date of claims 49-84 is the date they were filed, 3/14/03.

Bao et al. discloses an implantable device for treating an aperture in the annulus fibrosus of an intervertebral disc with all the elements of claims 49, 86, 87 and 88. See columns 7-8, lines 61-9 for the device comprising a body in the form of a cylindrical plug (width and height are the same). The plug has an interior end that is adapted to expand disproportionately more than the barrel such that the interior portion forms an internal lock upon insertion. This means

that in a delivery configuration, the device has a width (first dimension) no larger than the aperture it is being implanted into. Also, in an implanted configuration, the device has a height (second dimension) at an interior end that is larger than the aperture, thereby restricting the migration of intradiscal material through the aperture.



With respect to claim 50, the second dimension (height) lies along a different axis than the first dimension (width).

With respect to claims 51-53, the cylindrical plug in its unexpanded delivery configuration is certainly *capable* of subannular reorientation comprising rotation (about its longitudinal axis) or deformation.

Claim 54, see column 8, lines 1-2 for second dimension (height at interior end) resulting from expansion of the device from the delivery configuration. Also see column 4, lines 50-54.

Claims 55, 56 and 67-69 do not further structurally limit the device. How and when the aperture dimension is measured does not affect the structure of the device.

Claim 57, see column 5, line 34 for synthetic biocompatible material.

Claim 58, see column 5, line 43 for polyethylene.

Claim 59, see column 6, line 23 for bioresorbable material.

Claim 60, see column 5, line 57 for PTFE.

Claim 61, see column 4, lines 35-40 for material facilitating regeneration of disc tissue.

Claim 62, see column 4, lines 50-53. Because the device material will expand upon release of a constraining means, it is inherent that the material is of a shape memory material.

Claims 70 and 71, see column 5, lines 31-58 and column 7, line 57 for polymeric sheet.

Claim 75, see column 14, line 21 for porous mesh.

Claim 76, see column 5, lines 36-39 for fibrous material.

Claim 77, see column 4, lines 22-49 for biocompatible fabric.

Claim 78, see column 14, lines 19-27 for attachment element.

Claims 79 and 80 do not further structurally limit the device. The anatomical features to which the attachment element is fixating the device to do not affect the structure of the device.

Claims 81-85, see column 14, lines 17-24 for attachment means that well known in the art as equivalents.

10. Claims 49-64, 67-71 and 75-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambrecht (USPN 6,425,919).

Lambrecht discloses a disc herniation constraining device with all the elements of claims 49, 86, 87 and 88. See Figures 29B-C for a device (12) for treating a spinal disc annulus having an aperture (16). The device comprises a delivery configuration (Figures 29A-29B) wherein the device has a width (first dimension) no larger than the aperture it is being implanted into (the width is the width of the delivery tool). Also, the device has an implanted configuration (Figures 29C-29D) wherein the device has a height (second dimension) that is larger than the aperture. See column 17, lines 1-4 for the device (12) spanning the aperture (16) and extending along the

interior aspect (36) of the annulus (10) until it contacts healthy tissues on all sides of the aperture (16), thereby restricting the migration of intradiscal material therethrough.

With respect to claim 50, the second dimension (height) lies along a different axis than the first dimension (width).

With respect to claims 51-53, the device in its unexpanded delivery configuration is certainly *capable* of subannular reorientation comprising rotation (about its longitudinal axis) or deformation.

Claim 54, see column 19, lines 44-47 for second dimension (height) resulting from expansion of the device from the delivery configuration.

Claims 55, 56 and 67-69 do not further structurally limit the device. How and when the aperture dimension is measured does not affect the structure of the device.

Claims 57-60, 70, 71 and 75-77, see columns 15-16, lines 58-3 and column 17, lines 22-25, 38-41 for material limitations.

Claim 61, see column 21, lines 28-29 for material facilitating regeneration of disc tissue.

Claims 62 and 63, see column 17, lines 39-42 the device material being of the shape memory material nitinol.

Claim 64, see Figure 29C, columns 15-16, lines 65-1 and column 19, lines 44-47 for device comprising flexible bladder (12').

Claim 78, see column 15, lines 52-53 for attachment element.

Claims 79 and 80 do not further structurally limit the device. The anatomical features to which the attachment element is fixating the device to do not affect the structure of the device.

Claims 81-85, see column 15, lines 52-53 for attachment means that well known in the art as equivalents.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. in view of Lambrecht (USPN 6,425,919).

Bao et al. discloses an implantable device for treating the annulus of a patient's intravertebral disc with all the elements of claim 49, but is silent to the device comprising nitinol, as required by claim 63. Lambrecht teaches a disc annulus barrier (53) that comprises nitinol in order to aid in the expansion of the barrier. See column 17, lines 26-42. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lambrecht to make the device of Bao et al. at least in part of nitinol in order to impart a further expansion property to the material. Nitinol is well known in the art as a shape memory material.

13. Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. in view of Ferree (USPN 6,245,107, as cited in applicant's IDS).

Bao et al. discloses an implantable device for treating the annulus of a patient's intravertebral disc with all the elements of claim 49, but is silent to the additional limitations of the device being formed at least in part from allograft, autograft or xenograft, as required by claims 72-74, respectively. Ferree teaches an intervertebral disc annulus device made of natural materials including human and non-human, in order to promote tissue ingrowth. This obviously includes allograft, autograft or xenograft. See column 6, lines 5-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Ferree to make the device of Bao et al. at least in part of allograft, autograft or xenograft in order to promote tissue ingrowth.

14. Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht in view of Felt et al. (WO 98/20939 A2).

Lambrecht discloses a disc herniation constraining device with all the elements of claim 49, but is silent to the additional limitation of the bladder further comprising fluid, as required by claim 65, and of that fluid being a gel, as required by claim 66. Felt et al. teaches a balloon that is inserted into an aperture of a disc annulus and then filled with hydrogel to cure in order to permanently retain the hydrogel in apposition to the annulus aperture. See Figure 5, page 10, lines 14-15, page 57, lines 13-29, and page 43, lines 20-29. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Felt et al. to modify the device of Lambrecht by including hydrogel into the internal cavity of the balloon (12') in order to permanently retain the hydrogel, and therefore the implant, in position next to

the aperture. Also, the examiner contends that by adding the hydrogel, upon curing, it will provide the device with added strength to resist tearing or breaking.

15. Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambrecht in view of Ferree.

Lambrecht discloses an implantable device for treating the annulus of a patient's intravertebral disc with all the elements of claim 49, but is silent to the additional limitations of the device being formed at least in part from allograft, autograft or xenograft, as required by claims 72-74, respectively. Ferree teaches an intervertebral disc annulus device made of natural materials including human and non-human, in order to promote tissue ingrowth. This obviously includes allograft, autograft or xenograft. See column 6, lines 5-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Ferree to make the device of Lambrecht at least in part of allograft, autograft or xenograft in order to promote tissue ingrowth.

Allowable Subject Matter

16. Claims 46-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay

Art Unit 3738

David J. Isabella
Primary Examiner